

K071325

JUL 26 2007

### 510(k) Summary

**Preparation Date:** July 10, 2007

**Applicant/Sponsor:** Biomet Trauma (formerly known as EBI Trauma)  
100 Interpace Parkway  
Parsippany, NJ 07054

**Contact Person:** Debra L. Bing  
Director, Regulatory Affairs  
Biomet Trauma  
973.299.9300

**Proprietary Name:** Biomet Variable Locking Plate System

**Common Name:** Metallic bone plates and screws

**Classification Name:** Single/multiple component metallic bone fixation appliances and accessories,  
21 CFR §888.3030

**Product Code(s):** HRS, HWC

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

EBI Anterior Cervical Plate System (Cyprus)	K060379	EBI, L.P.
IQL Stainless Steel Bone Plates and Screws	K020221	Biomet Orthopedics, Inc.

**Device Description:** The Biomet Variable Locking Plate System is an internal fixation system comprised of Ti-6Al-4V and consisting of various-sized plates and screws.

**Indications for Use:** The Biomet Variable Locking Plate System is used for adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones.

**Summary of Technologies:** The technological characteristics of the Biomet Variable Locking Plate System are the same as, or similar to, the predicate devices.

**Non-Clinical Testing:** Engineering analyses comparing the Biomet Variable Locking Plate System to a predicate device were conducted to determine substantial equivalence. The results indicated that the Biomet Variable Locking Plate System was functional within its intended use.

**Clinical Testing:** None provided as a basis for substantial equivalence.

All trademarks are property of Biomet, Inc. unless otherwise noted.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet Trauma  
% Ms. Susan Alexander  
Senior Regulatory Specialist  
P.O. Box 587  
Warsaw, Indiana 46581-0587

JUL 26 2007

Re: K071325

Trade/Device Name: Biomet Variable Locking Plate System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances  
and accessories  
Regulatory Class: II  
Product Code: HRS, HWC  
Dated: May 9, 2007  
Received: May 10, 2007

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

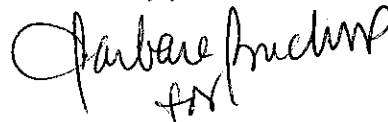
Page 2 - Ms. Susan Alexander

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071325

Device Name: Biomet Variable Locking Plate System

### Indications For Use:

The Biomet Variable Locking Plate System is used for adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones.

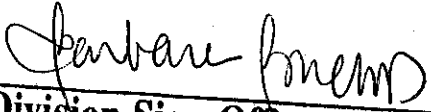
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K071325

Page 1 of 1